

in 27 patients (111 lesions). The mean stent length per patient was 87.4 ± 45.2 mm. At 30 days the cumulative MACE rates were 10.3%: 7.1% patients developed a non-Q, 1.9% a Q-wave MI, 0.6% died for non-cardiac reasons and 0.6% had a repeat revascularization. Clinical follow-up was obtained in all eligible 112 patients treated on 359 lesions at a mean time of 6.5 ± 2.2 months. The cumulative MACE rate was: 3 deaths (2.7%, 1 for cardiac reasons) and 4 (3.6%) MI. Target lesion revascularization (TLR) was performed in 24 (6.7%) lesions in 16 patients (14.3%). Target vessel revascularization was required in 18 (16.1%) patients due to TLR of lesions treated with SES or to disease progression (1.8% of patients). Cumulative total MACE rate was 22.3%. Cox regression analysis revealed total stent length per patient as the most powerful independent predictor of MACE. Overall stent thrombosis occurred in 3 (1.9%) patients.

CONCLUSION

Multivessel SES implantation can be safely performed on patients with complex coronary artery disease. The need for revascularization increases due to cumulative effect of TLR on patients with multiple lesions.

1044-61

Creatine Kinase-MB Enzyme Elevation After Percutaneous Coronary Interventions Using Sirolimus-Eluting Stents

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Objective: To evaluate predictors of periprocedural creatine kinase MB isoenzyme (CK-MB) elevation following implantation of sirolimus-eluting stents (SES).

Methods: We studied 320 consecutive patients who underwent SES implantation in 722 coronary lesions between April 2002 and January 2003. Univariate and multivariate logistic regression analyses were used to determine independent predictors of CK-MB elevation from clinical, angiographic and procedural covariates.

Results: CK-MB elevation > 3 times upper limit of normal occurred in 42 patients (13.1%). Those patients less frequently received elective glycoprotein IIb/IIIa agents (GP IIb/IIIa) (19% vs. 43%, $P=0.001$) and had longer SES implanted (total stent length per patient 86 vs. 59 mm, $P=0.001$). Univariate predictors of CK-MB elevation were: multivessel disease, OR 2.05 (95%CI 1.05-3.99, $P=0.032$); number of treated lesions, OR 1.43 (95%CI 1.17-1.76, $P=0.001$); de-novo lesion, OR 1.80 (95%CI 1.02-3.18, $P=0.034$); total stent length per patient, OR 1.13 (95%CI 1.01-1.20, $P=0.001$) and elective use of GP IIb/IIIa, OR 0.31 (95%CI 0.14-0.70, $P=0.003$). Multivariate analysis indicated that total stent length per patient (OR 1.02 (95%CI 1.01-1.03, $P=0.001$, predisposing factor) and elective use of GP IIb/IIIa (OR 0.21 (95%CI 0.08-0.50, $P=0.001$, protective factor) were independent predictors of CK-MB elevation. At 30 days and 9.5 months follow-up patients with and without periprocedural myonecrosis had similar composite MACE (death/myocardial infarction/repeat revascularization, 2.4% vs. 1.4%, $P=0.65$ and 21.4% vs. 16.9%, $P=0.47$, respectively).

Conclusion: In patients treated with SES, CK-MB elevation correlates with implantation of longer stents, while elective use of GP IIb/IIIa lowers that risk.

1044-62

Post-Market Surveillance of the CYPHER Sirolimus-Eluting Stent: One-Month Clinical Results From the United States

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Background: e-CYPHER is a global, internet-based registry collecting data on the use of the CYPHER™ Sirolimus-eluting Stent (CYPHER) in routine clinical practice. In the US, e-CYPHER is the database tool for the FDA-mandated post market surveillance requirement.

Methods: The US post market surveillance includes 2000 patients at up to 75 centers. Data are recorded in the e-CYPHER registry from consecutive patients treated with at least one CYPHER stent, with clinical follow-up at 1, 6 and 12 months. Demographic, treatment, and adverse event information are collected. Events reported from US patients are adjudicated by an independent clinical events committee.

Results: Enrollment into the US registry began on August 6, 2003. Currently, 110 patients have been enrolled at 6 sites. One month data from the US will be available at the time of presentation. Site reported one month event rates from 3330 patients treated at sites throughout Europe, Latin America, Asia Pacific and Middle East are presented below.

One Month Event Rates (3330 patients)	
MACE (%)	1.80
Death (%)	0.66
MI (%)	0.69
TLR (%)	0.24
CABG (%)	0.21
SAT (%)	0.87

Conclusions: The e-CYPHER registry is the largest ongoing registry of drug-eluting stent usage, and will provide ongoing safety information for the CYPHER stent.

POSTER SESSION

1062

Renal Insufficiency, Diabetes Mellitus, and Contrast-Induced Nephropathy Associated With Percutaneous Coronary Intervention

Monday, March 08, 2004, 9:00 a.m.-11:00 a.m.

Morial Convention Center, Hall G

Presentation Hour: 9:00 a.m.-10:00 a.m.

1062-41

The Impact of Renal Insufficiency on Long-Term Survival of Patients With Diabetes Undergoing Percutaneous Coronary Intervention

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Introduction: Diabetes and renal insufficiency are each associated with an increased risk of mortality among patients with coronary artery disease (CAD). However, the impact of coexistent renal disease and diabetes in patients with established CAD is not well understood. We sought to evaluate the impact of renal insufficiency on survival of patients with diabetes and CAD. **Methods:** Three hospitals in New York City contributed data on 1142 consecutive diabetic patients undergoing percutaneous coronary intervention (PCI) in 1998-9. Renal disease was defined by a creatinine > 2.5 mg/dl and included patients on chronic dialysis. The primary end-point was all-cause mortality at 3-year follow-up. **Results:** Among diabetics, renal disease was present in 75 patients (6.6%). There was no difference in age, race, or gender between groups. Diabetics with renal disease were more commonly obese (41.3% vs. 30.7%, $P=0.079$) and less likely to be smokers (1.3% vs. 9.4%, $P=0.018$). Hypertension and stroke were not different between groups. Patients with renal disease had a greater prevalence of vascular disease (25.3% vs. 9.7%, $P<0.001$), prior heart failure (22.7% vs. 7.7%, $P<0.001$) and previous cardiac surgery (33.3% vs. 21.6%, $P=0.019$). Diabetics with renal disease presented more often with 3-vessel CAD (36% vs. 23%, $P=0.009$). Mean ejection fraction was lower in diabetics with renal disease (46% vs. 50%, $P<0.001$). Angiographic success was 97% in both groups. In-hospital mortality was significantly greater among diabetics with renal disease than diabetics without renal impairment (6.7% vs. 0.6%, $P<0.001$). At 3-year follow-up, mortality for diabetics with renal disease was 44% vs. 11% in diabetics without renal impairment (log-rank $P<0.0001$). On Cox proportional hazards analysis, renal disease among diabetics was an independent predictor of mortality (Hazard Ratio, 3.067, 95% Confidence Interval, 1.987-4.733, $P<0.001$). **Conclusion:** Renal disease in diabetics with CAD is independently associated with a 3-fold increase in the hazard of death. The increased mortality of CAD diabetics with renal impairment should stimulate further research concerning appropriate treatment and surveillance regimens.

1062-42

Adverse Events in Patients With Normal Renal Function Are Increased With Modest Increases in Creatinine Clearance After Percutaneous Coronary Intervention

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Background: Creatinine clearance (CrCl) reduction after percutaneous coronary intervention (PCI) is associated with increases in adverse events in patients with chronic kidney disease. However, the impact of CrCl changes after PCI in patients with normal baseline renal function is not well defined.

Methods: Data was prospectively collected from 1993 to 2003 on 20,479 patients undergoing PCI. Patients were excluded for an estimated baseline CrCl ≤ 90 ml/min, prior history of renal failure or dialysis, coronary artery bypass surgery, ejection fraction $\leq 30\%$, shock, no reflow, and residual stenosis $\geq 50\%$. Patients were grouped by CrCl reduction for comparison. Multivariate analysis was used to determine the impact on in-hospital adverse events.

Results: The incidence of a $\geq 25\%$ CrCl reduction after PCI in patients with previously normal renal function was 0.08% (262/3658). Independent predictors with an odds ratio ≥ 2 were: male gender (P value <0.001), intra-aortic balloon pump use (P value $=0.01$), and age over 70 (P value $=0.0004$). Patients with a decrease in CrCl had increased events as shown below.

Adverse Events with Decreasing Creatinine Clearance				
		Creatinine Clearance Decrease		
		0-25%	> 25-<50%	>50%
		N=3396	N=231	N=31
Adverse Events				P value
Death		0.3%	0.9%	13.0%
Bleeding		0.7%	1.3%	16.0%
Hospitalization >4days		12%	30%	56%
Myocardial Infarction		0.5%	0.4%	3.2%
Reocclusion		0.4%	0.4%	0.0%